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10/737,324

12/16/2003

Edward H. Cully

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EXAMINER

MATTHEWS, WILLIAM H

ART UNIT

PAPER NUMBER

3774

MAIL DATE

DELIVERY MODE

05/15/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--|-------------------------------------|--|
| Office Action Summary | Application No. 10/737,324 | Applicant(s) CULLY ET AL. | |
| | Examiner William H. Matthews (Howie) | Art Unit 3774 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 October 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-13,15-19,21 and 23-28 is/are pending in the application.
- 4a) Of the above claim(s) 7 and 25-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-6,8-13,15-19,21,23 and 24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3-27-08</u> . | 6) <input type="checkbox"/> Other: _____ |

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are not persuasive.

Regarding the 112, 1st paragraph rejection Applicant contends the specification do not require the means must be used exclusively and therefore provides support for the combination. Examiner disagrees because Applicant has not shown where the specification or original claims disclose a combination of anisotropic material with reduced thickness or perforations. Indeed, the specification only teaches separate embodiments which are not described in a combination as presently claimed.

Regarding Smith, Applicant suggests the use of anisotropic materials teaches away from a splittable prosthesis, and further notes the sealing methods of Smith would render the device more resistant to splitting. Examiner disagrees with this analysis because the material choice does not affect the ability of the device to split at the seams. Furthermore, a device which is *more resistant* to splitting does not prevent or preclude the ability of the device to split. Smith discloses various sealing means such as compression or bonding with adhesives or polymer solvents. Applicant has not shown these methods to render the device **incapable** of splitting. See MPEP 2113 & 2114 regarding product by process and functional language or intended use recitations.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 23 and 24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The combination of means for splitting including reduced thickness or a row of perforations **in combination with** anisotropic material is not supported by applicant's specification. Examiner has reproduced the portion of the specification pertaining to the anisotropic material as set forth in applicant's specification. Applicant sets forth the embodiment for using a tape that is helically wrapped about the stent:

Figure 4C shows a device 10 wherein a graft material 18 is provided having a node 42 and fibril 44 microstructure (e.g., ePTFE), of which a small sample area 18el is shown enlarged. This graft material 18 is oriented so as to be weaker in the longitudinal direction than in the radial (circumferential) direction. The ePTFE microstructure shown has a uniaxial microstructure, meaning that the fibrils are oriented primarily in a single direction. The graft material is thus amenable to splitting in the same direction as its direction of greatest strength (i.e., the direction of orientation of the fibrils). This orientation allows for the possibility of the graft material 18 splitting or separating between adjacent windings of the stent component 14 during removal of the stent in the manner previously described (i.e., cohesively disassembling). A preferred method of using such a node and fibril microstructure graft material is to use a film such as an ePTFE film, that has been cut into a long, narrow tape with the length of the tape parallel to the direction of the fibrils. This tape can be used as a graft

covering either over or beneath the stent component 14, or both over and beneath stent component 14, and is applied as a helical wrap with the pitch of the helix equal to and parallel to that of the helical pitch of the serpentine stent wire. This allows for disruption of the graft material 18 parallel to the pitch of the serpentine stent winding 14, by splitting of the tape parallel to its length (i.e., parallel to the direction of the fibrils) during stent removal, generally as shown by Figure 2.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

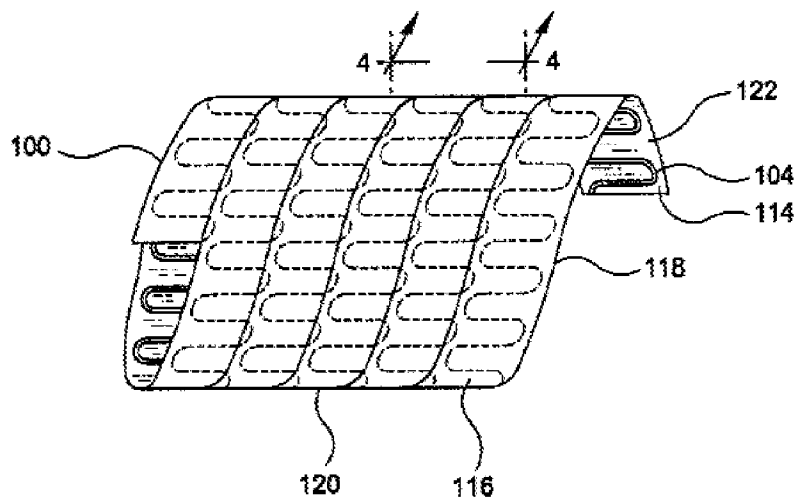
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1,3-6,8-13,15-19,21 are rejected under 35 U.S.C. 102(b) as being anticipated by Smith (6364904).

Smith discloses an endoprosthesis having a longitudinal direction and a circumferential direction, said endoprosthesis comprising: a stent component having a small delivery profile and an enlarged deployed profile, said stent component having adjacent elements with space between the adjacent elements; and a graft material attached to the stent component covering the space between the adjacent stent elements to form a substantially integral and continuous luminal surface; wherein said graft material has anisotropic strength properties and is oriented so as to be weaker in the longitudinal direction than in the circumferential direction; and wherein following

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deployment, the endoprosthesis is adapted to be cohesively disassembled by splitting of the graft material between the adjacent elements of the stent.



Claims 3 and 4, the helically wrapped eptfe along with the stent would be removable at a profile less than the delivery profile and a small delivery profile.

Claim 4, it is not clear what constitutes "small delivery profile".

Claim 5, due to the helical wrapping of the eptfe tape, the disassembly of the graft would be in a helical fashion.

Claim 6, splitting the seams of the overlaps would allow the graft to be removed in a single piece.

Claims 8 and 9, the length of the disassembled graft would inherently exhibit a length greater than 100% of the original prosthetic configuration. Due to the length/diameter ratio of the graft, the expanded length of the ribbon would exceed 500% of the original length of the prosthesis.

Claim 10, the graft is fluid tight.

Claim 11, the eptfe graft is microporous to allow tissue growth.

Claims 12 and 13, the graft of Smith is capable of being shortened.

Claim 15, the graft of Smith when removed would exhibit the same effect on the tissues as that of applicant's since applicant's device and that of Smith are essentially identical.

Claim 16, the graft material of Smith is eptfe.

Claims 17-19, see helical windings of the tape of Smith.

Claim 21, see rejection to claim 16 supra.

Conclusion

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Matthews (Howie) whose telephone number is 571-272-4753. The examiner can normally be reached on Monday-Friday 10-6:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David J. Isabella can be reached on 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/William H. Matthews/
Primary Examiner
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